mission. We should approve H.R. 3034 today so that we can ensure a timely reauthorization of the Bone Marrow Registry.

Ms. MCCARTHY of Missouri. Mr. Speaker, I rise today in support of H.R. 3034, the National Bone Marrow Donor Registry Reauthorization Act.

I want to commend the work of the co-sponsors of this legislation, the Representative of Florida, and Representative of New York. Your leadership on this issue has been remarkable and I commend your efforts.

It is a tragedy for Americans in need of bone marrow or stem cell donation to remain unconnected with willing donors. The National Bone Marrow Donor Registry has helped connect thousands of Americans in need of assistance with donors across the country. The additional resources this bill authorizes will help us expand this network and save even more lives.

I want to particularly commend the Registry's effort to recruit minority donors for their database. Blood diseases extract an especially heavy toll on minority populations, and improving the diversity of the donor pool should be an important part of our response to this problem.

Mr. Speaker, I want to commend the efforts of St. Luke's Hospital in Kansas City. Their Kansas City Blood and Marrow transplant program recruits new donors, finds matches, and coordinates the donation process. Since its inception in 1996, the Transplant Center at St. Lukes has performed over 450 transplants and connected thousands in our region with needed care. As a result of their hard work, the Center has been named a member of the United Resource Network centers of excellence program. These courageous efforts save thousands of lives each year. I congratulate them for being a model to our Nation.

Mr. Speaker, this bipartisan legislation is vital. I urge my colleagues to join me today in support of H.R. 3034.

Mr. TOM DAVIS of Virginia. Mr. Speaker, I rise today in strong support of H.R. 3034, the National Bone Marrow Donor Registry Reauthorization Act.

Today we are able to prolong hope for so many individuals waiting for a match to their bone marrow by reauthorizing the National Bone Marrow Donor Registry for another five years. For many people waiting for a transplant due to various illnesses, the task of finding a donor is a long and costly process. Each year two-thirds of patients awaiting bone marrow transplants are unsuccessful in finding a match within their family. This is why the establishment of a national registry was crucial.

About seventy percent of leukemia and other blood disorder patients do not find a match within their family. A match would be someone with certain white blood cells, called antigens, which are similar or identical to the patient's. These transplants enable patients the opportunity to live a full life, whereas without the transplant they would have little or no chance of survival.

From the organization of a donor registry through the United States Navy in 1986 to this current extension of the National Registry, it is clear that Congress takes this issue to heart. Each member of this House has someone in their district who has been touched by one of the debilitating diseases that need a bone marrow transplant, often as a last option.

Mr. Speaker, in closing, I would like to thank Chairman YOUNG for his leadership on the National Bone Marrow Donor Registry Reauthorization Act. Because of his family's own experience with the seriousness of bone marrow transplants, he has emerged as a leader in the issue and is committed to the cause. I urge all my colleagues to support this important reauthorization.

Ms. BORDALLO. Mr. Speaker, I rise today in support of H.R. 3034 which reauthorizes the National Bone Marrow Donor Registry. I commend Chairman YOUNG for his leadership in this critical program. Through his efforts in establishing the National Bone Marrow Donor Registry he has given countless people another chance at life.

Through the recruitment of the National Marrow Donor Program (NMDP), which manages the Registry, patients there are over 5 million potential donors. Through NMDP outreach efforts in 19 countries, patients have access to an additional 2.5 million potential donors. In fact, approximately 40 percent of transplants facilitated by NMDP involves a U.S. patient receiving stem cells from an international donor or an international donor receiving stems cells from a U.S. donor.

The importance of the Registry cannot be overstated and I commend and fully support the efforts of the National Marrow Donor Program for their recruitment efforts, especially for their efforts to recruit potential donors from diverse racial or ethnic groups.

The critical need for donors of African-American, Asian/Pacific Islander, Hispanic, American Indian/Alaska Native descent was made clear to me by the story of a five-year-old little girl from Guam whose life was cut short by leukemia.

Her name was Justice Taitague. Her best chance for life was a marrow transplant from a member of her ethnic group. The donor list at the time could not provide a match, but everyone involved in her care would not give up. Through the efforts of Dr. Thomas Shieh, the Guam Medical Society, and the National and Hawaiian Marrow Donor Programs, the first ever marrow drive on Guam was held on her behalf. This ''Drive for Justice'' registered thirty-four hundred volunteers in just three days.

Tragically, she passed away less than a week after the drive. But her life has given hope to others of Asian/Pacific Island descent needing a stem-cell transplant and helped us to understand the importance of the National Marrow Donor Program.

Mr. Speaker, I fully support H.R. 3034 to reauthorize the National Marrow Donor Registry. There is still a critical need for donors from the Asian, Pacific Islander and other minority communities to give the gift of life. Join the Registry.

Mr. BROWN of Ohio. Mr. Speaker, I yield back the balance of my time.

Mr. UPTON. Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Michigan (Mr. UPTON) that the House suspend the rules and pass the bill, H.R. 3034, as amended.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the bill, as amended, was passed.

A motion to reconsider was laid on the table.

ANIMAL DRUG USER FEE ACT OF 2003

Mr. UPTON. Mr. Speaker, I move to suspend the rules and pass the bill (H.R. 1260) to amend the Federal Food, Drug, and Cosmetic Act to establish a program of fees relating to animal drugs.

The Clerk read as follows:

H.R. 1260

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Animal Drug User Fee Act of 2003''.

SEC. 2. FINDINGS.

Congress finds as follows:

(1) Prompt approval of safe and effective new animal drugs is critical to the improvement of animal health and the public health.

(2) Animal health and the public health will be served by making additional funds available for the purpose of augmenting the resources of the Food and Drug Administration that are devoted to the process for review of new animal drug applications.

(3) The fees authorized by this title will be dedicated toward expediting the animal drug development process and the review of new and supplemental animal drug applications and investigational animal drug submissions as set forth in the goals identified, for purposes of part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, in the letters from the Secretary of Health and Human Services to the Chairman of the Committee on Energy and Commerce of the House of Representatives and the Chairman of the Committee on Health, Education, Labor, and Pensions of the Senate as set forth in the Congressional Record.

SEC. 3. FEES RELATING TO ANIMAL DRUGS.

Subchapter C of chapter VII of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 379f et seq.) is amended by adding at the end the following part:

''PART 4—FEES RELATING TO ANIMAL DRUGS

''SEC. 739. DEFINITIONS.

''For purposes of this subchapter:

''(1) The term 'animal drug application' means an application for approval of any new animal drug submitted under section 512(b)(1). Such term does not include either a new animal drug application submitted under section 512(b)(2) or a supplemental animal drug application.

''(2) The term 'supplemental animal drug application' means—

''(A) a request to the Secretary to approve a change in an animal drug application which has been approved; or

''(B) a request to the Secretary to approve a change to an application approved under section 512(c)(2) for which data with respect to safety or effectiveness are required.

''(3) The term 'animal drug product' means each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code and product code portions of the national drug code, and for which an animal drug application or a supplemental animal drug application has been approved.

''(4) The term 'animal drug establishment' means a foreign or domestic place of business which is at one general physical location consisting of one or more buildings all of which are within 5 miles of each other, at which one or more animal drug products are manufactured in final dosage form.

''(5) The term 'investigational animal drug submission' means—

''(A) the filing of a claim for an investigational exemption under section 512(j) for a new animal drug intended to be the subject of an animal drug application or a supplemental animal drug application, or

''(B) the submission of information for the purpose of enabling the Secretary to evaluate the safety or effectiveness of an animal drug application or supplemental animal drug application in the event of their filing.

''(6) The term 'animal drug sponsor' means either an applicant named in an animal drug application, except for an approved application for which all subject products have been removed from listing under section 510, or a person who has submitted an investigational animal drug submission that has not been terminated or otherwise rendered inactive by the Secretary.

''(7) The term 'final dosage form' means, with respect to an animal drug product, a finished dosage form which is approved for administration to an animal without substantial further manufacturing. Such term includes animal drug products intended for mixing in animal feeds.

''(8) The term 'process for the review of animal drug applications' means the following activities of the Secretary with respect to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions:

''(A) The activities necessary for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

''(B) The issuance of action letters which approve animal drug applications or supplemental animal drug applications or which set forth in detail the specific deficiencies in animal drug applications, supplemental animal drug applications, or investigational animal drug submissions and, where appropriate, the actions necessary to place such applications, supplements or submissions in condition for approval.

''(C) The inspection of animal drug establishments and other facilities undertaken as part of the Secretary's review of pending animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

''(D) Monitoring of research conducted in connection with the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

''(E) The development of regulations and policy related to the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

''(F) Development of standards for products subject to review.

''(G) Meetings between the agency and the animal drug sponsor.

''(H) Review of advertising and labeling prior to approval of an animal drug application or supplemental animal drug application, but not such activities after an animal drug has been approved.

''(9) The term 'costs of resources allocated for the process for the review of animal drug applications' means the expenses incurred in connection with the process for the review of animal drug applications for—

''(A) officers and employees of the Food and Drug Administration, contractors of the Food and Drug Administration, advisory committees consulted with respect to the review of specific animal drug applications, supplemental animal drug applications, or investigational animal drug submissions, and costs related to such officers, employees, committees, and contractors, including costs for travel, education, and recruitment and other personnel activities,

''(B) management of information, and the acquisition, maintenance, and repair of computer resources,

''(C) leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance, and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies, and

''(D) collecting fees under section 740 and accounting for resources allocated for the review of animal drug applications, supplemental animal drug applications, and investigational animal drug submissions.

''(10) The term 'adjustment factor' applicable to a fiscal year refers to the formula set forth in section 735(8) with the base or comparator year being 2003.

''(11) The term 'affiliate' refers to the definition set forth in section 735(9).

''SEC. 740. AUTHORITY TO ASSESS AND USE ANIMAL DRUG FEES.

''(a) TYPES OF FEES.—Beginning in fiscal year 2004, the Secretary shall assess and collect fees in accordance with this section as follows:

''(1) ANIMAL DRUG APPLICATION AND SUPPLEMENT FEE.—

''(A) IN GENERAL.—Each person that submits, on or after September 1, 2003, an animal drug application or a supplemental animal drug application shall be subject to a fee as follows:

''(i) A fee established in subsection (b) for an animal drug application; and

''(ii) A fee established in subsection (b) for a supplemental animal drug application for which safety or effectiveness data are required, in an amount that is equal to 50 percent of the amount of the fee under clause (i).

''(B) PAYMENT.—The fee required by subparagraph (A) shall be due upon submission of the animal drug application or supplemental animal drug application.

''(C) EXCEPTION FOR PREVIOUSLY FILED APPLICATION OR SUPPLEMENT.—If an animal drug application or a supplemental animal drug application was submitted by a person that paid the fee for such application or supplement, was accepted for filing, and was not approved or was withdrawn (without a waiver or refund), the submission of an animal drug application or a supplemental animal drug application for the same product by the same person (or the person's licensee, assignee, or successor) shall not be subject to a fee under subparagraph (A).

''(D) REFUND OF FEE IF APPLICATION REFUSED FOR FILING.—The Secretary shall refund 75 percent of the fee paid under subparagraph (B) for any animal drug application or supplemental animal drug application which is refused for filing.

''(E) REFUND OF FEE IF APPLICATION WITHDRAWN.—If an animal drug application or a supplemental animal drug application is withdrawn after the application or supplement was filed, the Secretary may refund the fee or portion of the fee paid under subparagraph B if no substantial work was performed on the application or supplement after the application or supplement was filed. The Secretary shall have the sole discretion to refund the fee under this paragraph. A determination by the Secretary concerning a refund under this paragraph shall not be reviewable.

''(2) ANIMAL DRUG PRODUCT FEE.—Each person—

''(A) who is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product which has been submitted for listing under section 510, and

''(B) who, after September 1, 2003, had pending before the Secretary an animal drug application or supplemental animal drug application;

shall pay for each such animal drug product the annual fee established in subsection (b). Such fee shall be payable for the fiscal year in which the animal drug product is first submitted for listing under section 510, or is submitted for relisting under section 510 if the animal drug product has been withdrawn from listing and relisted. After such fee is paid for that fiscal year, such fee shall be payable on or before January 31 of each year. Such fee shall be paid only once for each animal drug product for a fiscal year in which the fee is payable.

''(3) ANIMAL DRUG ESTABLISHMENT FEE.—Each person—

''(A) who owns or operates, directly or through an affiliate, an animal drug establishment, and

''(B) who is named as the applicant in an animal drug application or supplemental animal drug application for an animal drug product which has been submitted for listing under section 510, and

''(C) who, after September 1, 2003, had pending before the Secretary an animal drug application or supplemental animal drug application,

shall be assessed an annual fee established in subsection (b) for each animal drug establishment listed in its approved animal drug application as an establishment that manufactures the animal drug product named in the application. The annual establishment fee shall be assessed in each fiscal year in which the animal drug product named in the application is assessed a fee under paragraph (2) unless the animal drug establishment listed in the application does not engage in the manufacture of the animal drug product during the fiscal year. The fee shall be paid on or before January 31 of each year. The establishment shall be assessed only one fee per fiscal year under this section, provided, however, that where a single establishment manufactures both animal drug products and prescription drug products, as defined in section 735(3), such establishment shall be assessed both the animal drug establishment fee and the prescription drug establishment fee, as set forth in section 736(a)(2), within a single fiscal year.

''(4) ANIMAL DRUG SPONSOR FEE.—Each person—

''(A) who meets the definition of an animal drug sponsor within a fiscal year; and

''(B) who, after September 1, 2003, had pending before the Secretary an animal drug application, a supplemental animal drug application, or an investigational animal drug submission,

shall be assessed an annual fee established under subsection (b). The fee shall be paid on or before January 31 of each year. Each animal drug sponsor shall pay only one such fee each fiscal year.

''(b) FEE AMOUNTS.—Except as provided in subsection (a)(1) and subsections (c), (d), (f), and (g), the fees required under subsection (a) shall be established to generate fee revenue amounts as follows:

''(1) TOTAL FEE REVENUES FOR APPLICATION AND SUPPLEMENT FEES.—The total fee revenues to be collected in animal drug application fees under subsection (a)(1)(A)(i) and supplemental animal drug application fees under subsection (a)(1)(A)(ii) shall be

$1,250,000 in fiscal year 2004, $2,000,000 in fiscal year 2005, and $2,500,000 in fiscal years 2006, 2007, and 2008.

''(2) TOTAL FEE REVENUES FOR PRODUCT FEES.—The total fee revenues to be collected in product fees under subsection (a)(2) shall be $1,250,000 in fiscal year 2004, $2,000,000 in fiscal year 2005, and $2,500,000 in fiscal years 2006, 2007, and 2008.

''(3) TOTAL FEE REVENUES FOR ESTABLISHMENT FEES.—The total fee revenues to be collected in establishment fees under subsection (a)(3) shall be $1,250,000 in fiscal year 2004, $2,000,000 in fiscal year 2005, and $2,500,000 in fiscal years 2006, 2007, and 2008.

''(4) TOTAL FEE REVENUES FOR SPONSOR FEES.—The total fee revenues to be collected in sponsor fees under subsection (a)(4) shall be $1,250,000 in fiscal year 2004, $2,000,000 in fiscal year 2005, and $2,500,000 in fiscal years 2006, 2007, and 2008.

''(c) ADJUSTMENTS.—

''(1) INFLATION ADJUSTMENT.—The revenues established in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for a fiscal year to reflect the greater of—

''(A) the total percentage change that occurred in the Consumer Price Index for all urban consumers (all items; United States city average) for the 12-month period ending June 30 preceding the fiscal year for which fees are being established; or

''(B) the total percentage change for the previous fiscal year in basic pay under the General Schedule in accordance with section 5332 of title 5, United States Code, as adjusted by any locality-based comparability payment pursuant to section 5304 of such title for Federal employees stationed in the District of Columbia.

The adjustment made each fiscal year by this subsection will be added on a compounded basis to the sum of all adjustments made each fiscal year after fiscal year 2004 under this subsection.

''(2) WORKLOAD ADJUSTMENT.—After the fee revenues are adjusted for inflation in accordance with subparagraph (1), the fee revenues shall be further adjusted each fiscal year after fiscal year 2004 to reflect changes in review workload. With respect to such adjustment:

''(A) This adjustment shall be determined by the Secretary based on a weighted average of the change in the total number of animal drug applications, supplemental animal drug applications for which data with respect to safety or effectiveness are required, manufacturing supplemental animal drug applications, investigational animal drug study submissions, and investigational animal drug protocol submissions submitted to the Secretary. The Secretary shall publish in the Federal Register the fees resulting from this adjustment and the supporting methodologies.

''(B) Under no circumstances shall this workload adjustment result in fee revenues for a fiscal year that are less than the fee revenues for that fiscal year established in subsection (b), as adjusted for inflation under subparagraph (c)(1).

''(3) FINAL YEAR ADJUSTMENT.—For fiscal year 2008, the Secretary may further increase the fees to provide for up to 3 months of operating reserves of carryover user fees for the process for the review of animal drug applications for the first 3 months of fiscal year 2009. If the Food and Drug Administration has carryover balances for the process for the review of animal drug applications in excess of 3 months of such operating reserves, then this adjustment will not be made. If this adjustment is necessary, then the rationale for the amount of the increase shall be contained in the annual notice setting fees for fiscal year 2008.

''(4) ANNUAL FEE SETTING.—The Secretary shall establish, 60 days before the start of each fiscal year beginning after September 30, 2003, for that fiscal year, animal drug application fees, supplemental animal drug application fees, animal drug sponsor fees, animal drug establishment fees, and animal drug product fees based on the revenue amounts established under subsection (b) and the adjustments provided under this subsection.

''(5) LIMIT.—The total amount of fees charged, as adjusted under this subsection, for a fiscal year may not exceed the total costs for such fiscal year for the resources allocated for the process for the review of animal drug applications.

''(d) FEE WAIVER OR REDUCTION.—

''(1) IN GENERAL.—The Secretary shall grant a waiver from or a reduction of 1 or more fees assessed under subsection (a) where the Secretary finds that—

''(A) the assessment of the fee would present a significant barrier to innovation because of limited resources available to such person or other circumstances,

''(B) the fees to be paid by such person will exceed the anticipated present and future costs incurred by the Secretary in conducting the process for the review of animal drug applications for such person,

''(C) the animal drug application or supplemental animal drug application is intended solely to provide for use of the animal drug in—

''(i) a Type B medicated feed (as defined in section 558.3(b)(3) of title 21, Code of Federal Regulations (or any successor regulation)) intended for use in the manufacture of Type C free-choice medicated feeds, or

''(ii) a Type C free-choice medicated feed (as defined in section 558.3(b)(4) of title 21, Code of Federal Regulations (or any successor regulation)),

''(D) the animal drug application or supplemental animal drug application is intended solely to provide for a minor use or minor species indication, or

''(E) the sponsor involved is a small business submitting its first animal drug application to the Secretary for review.

''(2) USE OF STANDARD COSTS.—In making the finding in paragraph (1)(B), the Secretary may use standard costs.

''(3) RULES FOR SMALL BUSINESSES.—

''(A) DEFINITION.—In paragraph (1)(E), the term 'small business' means an entity that has fewer than 500 employees, including employees of affiliates.

''(B) WAIVER OF APPLICATION FEE.—The Secretary shall waive under paragraph (1)(E) the application fee for the first animal drug application that a small business or its affiliate submits to the Secretary for review. After a small business or its affiliate is granted such a waiver, the small business or its affiliate shall pay application fees for all subsequent animal drug applications and supplemental animal drug applications for which safety or effectiveness data are required in the same manner as an entity that does not qualify as a small business.

''(C) CERTIFICATION.—The Secretary shall require any person who applies for a waiver under paragraph (1)(E) to certify their qualification for the waiver. The Secretary shall periodically publish in the Federal Register a list of persons making such certifications.

''(e) EFFECT OF FAILURE TO PAY FEES.—An animal drug application or supplemental animal drug application submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for filing by the Secretary until all fees owed by such person have been paid. An investigational animal drug submission under section 739(5)(B) that is submitted by a person subject to fees under subsection (a) shall be considered incomplete and shall not be accepted for review by the Secretary until all fees owed by such person have been paid. The Secretary may discontinue review of any animal drug application, supplemental animal drug application or investigational animal drug submission from a person if such person has not submitted for payment all fees owed under this section by 30 days after the date upon which they are due.

''(f) ASSESSMENT OF FEES.—

''(1) LIMITATION.—Fees may not be assessed under subsection (a) for a fiscal year beginning after fiscal year 2003 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2003 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.

''(2) AUTHORITY.—If the Secretary does not assess fees under subsection (a) during any portion of a fiscal year because of paragraph (1) and if at a later date in such fiscal year the Secretary may assess such fees, the Secretary may assess and collect such fees, without any modification in the rate, for animal drug applications, supplemental animal drug applications, investigational animal drug submissions, sponsors, animal drug establishments and animal drug products at any time in such fiscal year notwithstanding the provisions of subsection (a) relating to the date fees are to be paid.

''(g) CREDITING AND AVAILABILITY OF FEES.—

''(1) IN GENERAL.—Fees authorized under subsection (a) shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such fees are authorized to be appropriated to remain available until expended. Such sums as may be necessary may be transferred from the Food and Drug Administration salaries and expenses appropriation account without fiscal year limitation to such appropriation account for salary and expenses with such fiscal year limitation. The sums transferred shall be available solely for the process for the review of animal drug applications.

''(2) COLLECTIONS AND APPROPRIATION ACTS.—

''(A) IN GENERAL.—The fees authorized by this section—

''(i) shall be retained in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year, and

''(ii) shall only be collected and available to defray increases in the costs of the resources allocated for the process for the review of animal drug applications (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2003 multiplied by the adjustment factor.

''(B) COMPLIANCE.—The Secretary shall be considered to have met the requirements of subparagraph (A)(ii) in any fiscal year if the costs funded by appropriations and allocated for the process for the review of animal drug applications—

''(i) are not more than 3 percent below the level specified in subparagraph (A)(ii); or

''(ii)(I) are more than 3 percent below the level specified in subparagraph (A)(ii), and fees assessed for the fiscal year following the subsequent fiscal year are decreased by the

amount in excess of 3 percent by which such costs fell below the level specified in subparagraph (A)(ii); and

''(II) such costs are not more than 5 percent below the level specified in subparagraph (A)(ii).

''(3) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated for fees under this section—

''(A) $5,000,000 for fiscal year 2004;

''(B) $8,000,000 for fiscal year 2005;

''(C) $10,000,000 for fiscal year 2006;

''(D) $10,000,000 for fiscal year 2007; and

''(E) $10,000,000 for fiscal year 2008;

as adjusted to reflect adjustments in the total fee revenues made under this section and changes in the total amounts collected by animal drug application fees, supplemental animal drug application fees, animal drug sponsor fees, animal drug establishment fees, and animal drug product fees.

''(4) OFFSET.—Any amount of fees collected for a fiscal year under this section that exceeds the amount of fees specified in appropriations Acts for such fiscal year shall be credited to the appropriation account of the Food and Drug Administration as provided in paragraph (1), and shall be subtracted from the amount of fees that would otherwise be authorized to be collected under this section pursuant to appropriation Acts for a subsequent fiscal year.

''(h) COLLECTION OF UNPAID FEES.—In any case where the Secretary does not receive payment of a fee assessed under subsection (a) within 30 days after it is due, such fee shall be treated as a claim of the United States Government subject to subchapter II of chapter 37 of title 31, United States Code.

''(i) WRITTEN REQUESTS FOR WAIVERS, REDUCTIONS, AND REFUNDS.—To qualify for consideration for a waiver or reduction under subsection (d), or for a refund of any fee collected in accordance with subsection (a), a person shall submit to the Secretary a written request for such waiver, reduction, or refund not later than 180 days after such fee is due.

''(j) CONSTRUCTION.—This section may not be construed to require that the number of full-time equivalent positions in the Department of Health and Human Services, for officers, employees, and advisory committees not engaged in the process of the review of animal drug applications, be reduced to offset the number of officers, employees, and advisory committees so engaged.

''(k) ABBREVIATED NEW ANIMAL DRUG APPLICATIONS.—The Secretary shall—

''(1) to the extent practicable, segregate the review of abbreviated new animal drug applications from the process for the review of animal drug applications, and

''(2) adopt other administrative procedures to ensure that review times of abbreviated new animal drug applications do not increase from their current level due to activities under the user fee program.''.

SEC. 4. ACCOUNTABILITY AND REPORTS.

(a) PUBLIC ACCOUNTABILITY.—

(1) CONSULTATION.—In developing recommendations to Congress for the goals and plans for meeting the goals for the process for the review of animal drug applications for the fiscal years after fiscal year 2008, and for the reauthorization of sections 739 and 740 of the Federal Food, Drug, and Cosmetic Act (as added by section 3), the Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall consult with the Committee on Energy and Commerce of the House of Representatives, the Committee on Health, Education, Labor, and Pensions of the Senate, appropriate scientific and academic experts, veterinary professionals, representatives of consumer advocacy groups, and the regulated industry.

(2) RECOMMENDATIONS.—The Secretary shall—

(A) publish in the Federal Register recommendations under paragraph (1), after negotiations with the regulated industry;

(B) present the recommendations to the Committees referred to in that paragraph;

(C) hold a meeting at which the public may comment on the recommendations; and

(D) provide for a period of 30 days for the public to provide written comments on the recommendations.

(b) PERFORMANCE REPORTS.—Beginning with fiscal year 2004, not later than 60 days after the end of each fiscal year during which fees are collected under part 4 of subchapter C of chapter VII of the Federal Food, Drug, and Cosmetic Act, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report concerning the progress of the Food and Drug Administration in achieving the goals identified in the letters described in section 2(3) of this Act toward expediting the animal drug development process and the review of the new and supplemental animal drug applications and investigational animal drug submissions during such fiscal year, the future plans of the Food and Drug Administration for meeting the goals, the review times for abbreviated new animal drug applications, and the administrative procedures adopted by the Food and Drug Administration to ensure that review times for abbreviated new animal drug applications are not increased from their current level due to activities under the user fee program.

(c) FISCAL REPORT.—Beginning with fiscal year 2004, not later than 120 days after the end of each fiscal year during which fees are collected under the part described in subsection (a), the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made.

SEC. 5. SUNSET.

The amendments made by section 3 shall not be in effect after October 1, 2008, and section 4 shall not be in effect after 120 days after such date.

The SPEAKER pro tempore. Pursuant to the rule, the gentleman from Michigan (Mr. UPTON) and the gentleman from Ohio (Mr. BROWN) each will control 20 minutes.

The Chair recognizes the gentleman from Michigan (Mr. UPTON).

Mr. UPTON. Mr. Speaker, I yield myself such time as I may consume.

Mr. Speaker, as the lead sponsor of the Animal Drug User Fee Act of 2003, I am very pleased that we are taking up this bill on the House floor today. Closely modeled after the very successful Prescription Drug User Fee Act of 1992 for human drugs, the Animal Drug User Fee Act is designed to give the FDA's Center for Veterinary Medicine the resources and incentives needed to significantly improve the animal drug review process.

This bill was unanimously approved by the Committee on Energy and Commerce and is supported by a broad coalition of veterinary and producer groups, including the American Veterinary Medical Association and the American Farm Bureau, to name just two of the coalition members.

We would not be here on the floor today were it not for the strong bipartisan support that this legislation received in our committee. I would like to especially acknowledge my original cosponsor and author of the bill, the gentlewoman from Colorado (Ms. DEGETTE), committee chairman and ranking member, the gentleman from Louisiana (Mr. TAUZIN) and the gentleman from Michigan (Mr. DINGELL), our Subcommittee on Health Chair, the gentleman from Florida (Mr. BILIRAKIS), and the ranking member, the gentleman from Ohio (Mr. BROWN), who is here today, as well as the Members on both sides of the aisle who have cosponsored this legislation.

I am grateful, too, for the hard work of our committee staff, Brent Delmonte, Patrick Ronan, and John Ford and for the assistance we have received from the FDA and the Animal Health Alliance, particularly my staff, Jane Williams.

This legislation is sorely needed. Despite a statutory review time of 180 days, the average new animal drug application review currently takes about a year and a half and it may drag on for even longer. The slowdown in review time is jeopardizing the supply of new, safe and effective animal drugs needed to keep our pets, flocks and herds healthy and help provide American consumers with a safe and wholesome food supply.

Under this proposal, H.R. 1260, the additional revenues generated from fees paid by the pioneer animal drug industry would be dedicated for use in expediting the testing and review of new animal drugs in accordance with the performance goals that have been mutually agreed upon by the FDA and the animal drug industry.

As FDA Commissioner Mark McClellan has noted, a faster, more predictable review process is expected to spur more spending on research and development by the industry, promoting animal health by increasing the availability and diversity of new, safe and effective products.

I encourage my colleagues to vote for this much-needed bipartisan bill.

Mr. Speaker, I reserve the balance of my time.

Mr. BROWN of Ohio. Mr. Speaker, I yield myself such time as I may consume.

I rise in support of the Animal Drug User Fee Act. I thank the gentleman from Michigan (Mr. UPTON), also the gentleman from Florida (Mr. BILIRAKIS), the gentleman from Louisiana (Mr. TAUZIN), and the gentleman from Michigan (Mr. DINGELL) for their excellent work on this bill, especially the work that the gentlewoman from Colorado (Ms. DEGETTE) did as the author of this legislation.

H.R. 1260, Mr. Speaker, builds on a successful program for fee-funded expedited review of new human drug applications authorized in 1992 by something called the Prescription Drug User Fee Act, known as PDUFA, the congressional acronym that we are wont to do around here.

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We also reauthorized PDUFA some years ago. Congress has done a generally good job in speeding the approval process through the Prescription Drug User Fee Act. We have done not quite as good a job on expediting the approval of generic drugs, something that we need to work with the FDA to accelerate. It takes oftentimes as long as 18 months for a generic drug, something that costs consumers money by the slowness of the approval process.

I think this legislation on animal drugs is almost as important as those other two in terms of what it does with pets, what it does with zoos, and especially what it does with cattle and poultry. We have found, Mr. Speaker, in terms of an issue of antibiotic resistance where we have drugs that are on the market to cure animals, and sometimes those drugs have lost their effectiveness, as they have in the human population, and it is important that this legislation, H.R. 1260, the gentleman from Michigan's (Mr. UPTON) bill, get through Congress because it does, in fact, help to put more drugs on the market, more antibiotics in some indications to deal with the problems of antibiotic resistance.

We have had debates on the House floor that the gentleman from Florida (Mr. BILIRAKIS) has been part of on this whole issue of antibiotic resistance. We have seen the use of nontherapeutic drugs given for prophylactic purposes to cattle and poultry, given for growth treatments for cattle and poultry where there has been some residue from those drugs in the human population that have caused problems with antibiotic resistance, both in the animals and, after human consumption, in human beings. And it is especially important in light of the fact that we really have not fixed that problem. We still use far too many drugs for nontherapeutic purposes for cattle and poultry. It is important that this legislation passes because I think H.R. 1260 will help us deal with that.

I again ask for support for this legislation. It matters for our pets. It matters for zoos. It matters for production of cattle and poultry, and it ultimately matters in human health. I ask my colleagues to support H.R. 1260.

Mr. Speaker, I reserve the balance of my time.

Mr. UPTON. Mr. Speaker, I yield 3 minutes to the gentleman from Florida (Mr. STEARNS), my friend and an important supporter of this legislation, a member of the Committee on Energy and Commerce.

(Mr. STEARNS asked and was given permission to revise and extend his remarks.)

Mr. STEARNS. Mr. Speaker, I thank my distinguished colleague, who is chairman of the Telecommunications and the Internet Subcommittee and has been very active in this, for yielding me this time.

I obviously rise in support of H.R. 1260, the Animal Drug User Fee Act. By funding more FDA drug reviewers, Mr. Speaker, this act will help accelerate approval of important veterinarian drugs, resulting in the comfort and treatment of countless companions, pets, zoo animals and livestock.

This is very important. I am proud of the major veterinary school in my congressional district. The College of Veterinary Medicine in the University of Florida, Florida's only veterinary college, offers comprehensive service to the public through a fourfold mission: teaching, research, extension to the community, and patient care. And I am proud, Mr. Speaker, to be wearing a University of Florida tie in honor of their efforts and their leadership this morning. In fact, at this school, no creature is too small, too large, too pesky, or too dangerous for these fine veterinarians to treat, such as the endangered Florida panthers or even some exotic tropical birds. They have a Performance Animal Physiology Clinic, a Pharmacology and Disease Division, which, in fact, studies humane treatment of equine and greyhound species, athletes among pets. All of these animals, all of them, will benefit from innovative pharmaceuticals that are brought to the market in a more expedited manner.

In addition, one of the Nation's foremost thoroughbred horse industries is located in my hometown of Ocala, Florida. We are actually known as the horse capital of the world. We have 460 horse farms located in Ocala and in Marion County. The Florida Thoroughbred Breeders' and Owners' Association, Florida Thoroughbred Charities, and other equine-related concerns all serve a tremendously important part of our economy and this Nation's entertainment.

Do they demand the best medicines available in the world, available as quickly as possible for their pets and their assets? Absolutely. This bill will help, and that is why I am pleased to support this, and I thank the gentleman from Michigan (Mr. UPTON) for his very energetic work on behalf of this, and, of course, for my vet school and horse-owning friends in Florida's 6th Congressional District.

Mr. BROWN of Ohio. Mr. Speaker, I yield 4 minutes to the gentlewoman from Colorado (Ms. DEGETTE), author of the bill.

Ms. DEGETTE. Mr. Speaker, I would like to add my thanks to the gentleman from Michigan (Mr. UPTON) for taking the lead on this important piece of legislation and also for his diligence in making sure that it was brought to the floor today and the leadership on both sides of the aisle of the House subcommittee of the Committee on Energy and Commerce. It is always a pleasure to write and pass a bill with full bipartisan support.

The bill will improve the public's health, the efficiency of FDA's drug approval process, and perhaps most importantly to some, the health of the family pet and of our livestock in this country. In our society, pets have become even more important to Americans, and just like with humans, pharmaceuticals have helped improve the quality of our pets lives. My sister has a 16-year-old dog that is on insulin and several antiinflammatory drugs for arthritis just like senior citizens in this country, and her pet's health has been helped by these drugs, and thereby her family's situation has been improved, and they are happy to have their pet.

Unfortunately, up until now, drugs have not been able to be approved with speed like they are for humans, and the Animal Drug User Fee Act is closely modeled after the Prescription Drug User Fee Act, which was enacted 10 years ago. The purpose of this legislation is twofold: to increase resources available to the FDA so that it may speed up the approval process for pharmaceuticals, and also to maintain monitoring of the safety and efficacy of all pharmaceuticals. Decreasing delays of the approval process is a necessary step to keeping up with medical innovation, and this applies to drug for animals as well as for humans. The monitoring is an essential function that safeguards the public's health.

Ensuring the safety and efficacy of pharmaceuticals is of paramount importance. I am well aware of some of the issues with PDUFA, some of which were discussed by the gentleman from Ohio (Mr. BROWN), but I feel strongly that we must increase the FDA's work capacity. This bill has been carefully crafted on both sides of the aisle to avoid the problems of the past, and as my colleagues have heard, it was unanimously passed by the Committee on Energy and Commerce.

This bill, ADUFA, requires the Center for Veterinary Medicine at the FDA to meet performance standards in exchange for a 5-year infusion of funds.

By collecting fees from animal drug manufacturers, the FDA will be able to decrease the review time of new drug applications. These delays, which have been considerable in the past, prevent pharmaceuticals from entering the market. I am very pleased that the FDA has also worked very closely with us on the bill and is willing to implement the new program.

Increasing access to animal drugs not only helps lengthen and improve the lives of the family pet, but it will also, and perhaps more importantly, have a wide-ranging impact on our Nation's food supply and will improve prevention of food-borne disease epidemics. For example, for more than 40 years, antibiotics have played a critical role in keeping our Nation's food animals healthy. Without such treatments, illness would be transmitted to humans,

and the livestock market would be more susceptible to devastation. Therefore, we must continue to develop new treatments and quickly bring them to market, but we cannot do that without the speedy approval of the FDA.

I am particularly concerned about the food and medicine supply of this country. This commitment to safety that we are showing today through this legislation starts with the FDA's examination and approval of new pharmaceuticals and continues as these legal drugs are manufactured and distributed throughout the Nation. Commitment to safety must always be a part of the system.

The benefits of this bill are substantial, and, therefore, I am very pleased to cosponsor the bill. Vote yes on H.R. 1260, the Animal Drug User Fee Act.

Mr. GOODLATTE. Mr. Speaker, animal medicines are used to assist livestock producers raising and maintaining healthy, high quality stock and ultimately, in delivering safe and wholesome food to American dinner tables. They are also used to keep pets healthy, which contributes to the quality of life for millions of companion animal owners.

The Food and Drug Administration's Center for Veterinary Medicine (CVM) is currently experiencing unprecedented delays in its review of new product submissions. The delays are severe and problematic for the submission sponsors, for CVM, and for veterinarians, livestock and poultry producers, and pet owners in need of new and innovative products to combat animal disease—at a time when animal disease around the world is capturing headlines. The deadlock at the Center also has a chilling effect on the animal health industry's investment in important research and development, threatening the pipeline of products that will be important to livestock and poultry producers in managing their production in the future. The lack of these tools imperils not only animal health but also has implications for the food supply and food safety.

In 1966 Congress, with industry support, enacted the Animal Drug Availability Act to streamline drug review and approval procedures. Contrary to Congressional intent and despite additional resources, it is now more difficult than ever to get new products approved. Unfortunately, this situation is detrimental to veterinarians, to livestock and poultry producers, to food producers and to the public. As a result, it is important for Congress and the Administration to take action to ensure that the CVM can better manage its resources and personnel and make institutional changes to fulfill its mandated mission and responsibilities.

Modeled after the successful Prescription Drug User Fee Act, the Animal Drug User Fee Act will increase efficiencies in review times for new animal pharmaceuticals by providing CVM with additional resources to allow for improved communication between FDA and product sponsors and more expeditious FDA actions on applications.

Mr. Speaker, I congratulate Congressman UPTON for his leadership and that of the full Committee on Energy and Commerce for bringing this important legislation to the floor today and urge all Members to support it.

Mr. BROWN of Ohio. Mr. Speaker, I yield back the balance of my time.

Mr. UPTON. Mr. Speaker, I have no further requests for time, and I yield back the balance of my time.

The SPEAKER pro tempore. The question is on the motion offered by the gentleman from Michigan (Mr. UPTON) that the House suspend the rules and pass the bill, H.R. 1260.

The question was taken; and (two-thirds having voted in favor thereof) the rules were suspended and the bill was passed.

A motion to reconsider was laid on the table.

CONGRATULATING FORT DETRICK ON 60 YEARS OF SERVICE TO U.S.

Mr. BARTLETT of Maryland. Mr. Speaker, I move to suspend the rules and agree to the concurrent resolution (H. Con. Res. 271) congratulating Fort Detrick on 60 years of service to the United States, as amended.

The Clerk read as follows:

H. CON. RES. 271

Whereas April 10, 2003, was the 60th anniversary of the founding of the Army installation in Frederick, Maryland, named Fort Detrick;

Whereas Fort Detrick is designated as an Army Medical Installation and is home to the United States Army Medical Research and Materiel Command (USAMRMC), one of two campuses of the National Cancer Institute (NCI-Frederick), and 36 other organizations of the Department of Defense and other Federal departments;

Whereas the primary missions of the organizations at Fort Detrick include biomedical research and development, medical materiel management, and global telecommunications;

Whereas throughout that installation's 60-year history, the personnel and organizations assigned to that installation have contributed scientific breakthroughs and medical solutions for the Armed Forces and the Nation;

Whereas Fort Detrick is a focal point for the Nation's biomedical scientific leadership and has contributed extensively to protecting and improving public health in the United States;

Whereas Fort Detrick has been home to preeminent researchers in bacteriology, microbiology, clinical and preventative medicine, biochemistry, neurology, botany, virology, and genomics;

Whereas the research program at Fort Detrick was a pioneer in the laboratory facility designs, equipment, and procedures that are used for infectious disease research in laboratories worldwide;

Whereas researchers at Fort Detrick have improved public health throughout the world through the creation of botulinum antibodies, which have been used to treat both infant and adult victims of botulism;

Whereas the Venezuelan equine encephalitis vaccines, which were created at Fort Detrick, have been used to control human and animal outbreaks of Venezuelan equine encephalitis, and the Rift Valley Fever vaccines, which were also created at Fort Detrick, have been used to protect people in Egypt, Saudi Arabia, Yemen, and other countries who are at high risk of Rift Valley Fever;

Whereas, on January 27, 1969, the Office of the Surgeon General of the Army established the United States Army Medical Research Institute of Infectious Diseases (hereinafter in this resolution referred to as the ''Institute''), which is located at Fort Detrick and is the Department of Defense's lead laboratory for medical aspects of biological warfare defense;

Whereas when outbreaks of hantaviral disease began in the southwestern United States in 1993, the Institute was called upon by the Centers for Disease Control and Prevention and by various State health departments for consultations;

Whereas when the Ebola virus was first carried to the shores of the United States in late 1989 by a primate colony found in Reston, Virginia, it was researchers at the Institute who diagnosed and contained the outbreak;

Whereas the Institute also played a key role in the identification of and response to the initial outbreak of West Nile virus in New York;

Whereas the Institute continues its life-saving work by collaborating with the Centers for Disease Control and Prevention and the National Institutes of Health on the development of diagnostics and the evaluation of antiviral drugs for Severe Acute Respiratory Syndrome;

Whereas the Institute created a vaccine against hemorrhagic fever in the 1980s, which has possibly saved thousands of lives in Argentina, including the lives of agricultural workers at risk for exposure to this hemorrhagic fever virus;

Whereas the Institute was the only Federal laboratory to maintain a continuous diagnostic reference capability on a 24-hour per day basis after the attacks of September 11, 2001, and provided expertise in medical diagnostics and decontamination that was key to ensuring that congressional office buildings were safe to reoccupy after the anthrax mail attacks in the fall of 2001;

Whereas leading vaccine candidates for anthrax, plague, tularemia, and botulinum neurotoxins were all originally developed at the Institute;

Whereas the basic research program at the Institute is responsible for some of the most promising medical countermeasures against the leading biological threats that are on the ''A'' List of the Centers for Disease Control and Prevention;

Whereas the Institute has established a partnership with the National Institute of Allergy and Infectious Diseases of the National Institutes of Health to collaborate and accelerate biodefense research that will protect all Americans against the threat of biological and chemical attacks by terrorists;

Whereas in 1974, the United States Army Medical Materiel Agency was relocated to Fort Detrick and the Navy, Air Force, and Army all now conduct medical logistics planning and management at Fort Detrick in support of global military operations;

Whereas the Foreign Disease-Weed Science Research Unit of the Agricultural Research Service of the Department of Agriculture has conducted high-priority research in the Plant Pathogen Containment Facility at Fort Detrick for over 30 years, providing the agricultural community with basic epidemiological information and rapid diagnostic assays for exotic threatening and emerging crop diseases, such as Karnal bunt of wheat, soybean rust, potato late blight, and plum pox virus;

Whereas Company B, 4th Light Armored Reconnaissance Battalion, 4th Marine Division, United States Marine Corps Reserve, which has been assigned to Fort Detrick since October 1987, had a mission of reconnaissance and security in support of a Marine Air/Ground Task Force and received the Meritorious Unit Citation for its service during Operation Desert Storm;

Whereas the Army's 1108th Signal Brigade at Fort Detrick provides important strategic